



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q71975

Levon ARAKELYAN, et al.

Appln. No.: 10/662,345

Group Art Unit: 1631

Confirmation No.: 2068

Examiner: Not Yet Assigned

Filed: September 16, 2003

For: AN INTERACTIVE TECHNIQUE FOR OPTIMIZING DRUG DEVELOPMENT FROM THE PRE-CLINICAL PHASES THROUGH PHASE-IV

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.97 and 1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents, other than any U.S. patents and patent publications, is submitted herewith.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

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The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,

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Sheet 1 of 1

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First Named Inventor	Levon ARAKELYAN
Art Unit	
Examiner Name	
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U. S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	FOREIGN PATENT DOCUMENTS		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁵ (If known)	Publication Date MM-DD-YYYY			
		WO 02/051354 A2 /	07-04-2002	Robert Becker		
		WO 97/44752 A1 /	11-27-1997	Kornman et al		
		WO 01/00083 A1 /	01-04-2001	Thomas et al		

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NON PATENT LITERATURE DOCUMENTS

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	1.	FDA, CENTER FOR DRUG EVALUATION AND RESEARCH (CDER), Drug Development Process for Investigational New Drugs, http://www.fda.gov/cder/handbook/develop.htm , pp.3-28	
	2.	DEPARTMENT OF HEALTH AND HUMAN SERVICES, FDA, International Conference on Harmonization: Guidance on General Considerations for Clinical Trials, Federal Register Wednesday, December 17, 1997, pp. 66113-66119, Vol. 62, No. 242	
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Levon ARAKELYAN JAN 06 2004

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	11	Z. AGUR, Use of mathematical models for analyzing host-specific parasitaemia profiles in African trypanosomes, Parasitology Today, 1992, pp. 128-129, vol. 8	
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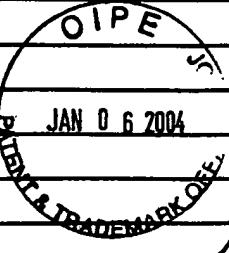
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	38	D. BERRY, Adaptive Trials and Bayesian Statistics in Drug Development, Biopharmaceutical Report, 2001, pp. 1-11 vol. 9(2)				/
	39	D. BERRY, General Keynote: Clinical Trial Design, Gynecological Oncology, 2003, pp. S114-S116, vol. 88				/
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